

Remarks

Reconsideration of this Application is respectfully requested.

Claims 1-13, 18-21, 26, 29-32 and 34-40 are pending in the application, with claims 1, 2, 6, 7 and 26 being the independent claims.

A Request for Continued Examination (RCE) is being filed concurrently herewith. Therefore, the finality of the Office Action mailed December 31, 2002 should be withdrawn and this Reply should be entered and considered. *See* 37 C.F.R. § 1.114(d).

Based on the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding rejections and that they be withdrawn.

I. Double Patenting

The Examiner has maintained the rejection of claims 1-13, 18-21, 26, 29-32 and 34-38 under the judicially-created doctrine of obviousness-type double patenting. (*See* Paper No. 18, Page 2.) Applicants respectfully request that this rejection be held in abeyance until the remaining outstanding issues in this application are resolved.

II. Claim Rejections Under 35 U.S.C. § 102

Claims 1, 2, 12, 13, 26 and 34-38 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by DIFCO manual in light of *Dyas et al.*, *Photochemistry* 35:655-660 (1994) (hereinafter "Dyas"). (*See* Paper No. 18, page 3.) Applicants respectfully traverse this rejection.

Under 35 USC § 102, a claim can only be anticipated if every element in the claim is expressly or inherently disclosed in a single prior art reference. *See Kalman v. Kimberly Clark Corp.*, 713 F.2d 760, 771 (Fed. Cir. 1983), *cert. denied*, 465 U.S. 1026 (1984). Since the DIFCO manual does not teach or suggest all of the elements of Applicants' claims, the DIFCO manual cannot and does not anticipate Applicants' claims.

The present claims are directed to cell culture media and compositions that are capable of supporting the cultivation of an animal cell *in vitro*. The compositions described in the DIFCO manual are used to culture yeasts and molds and are not capable of supporting the cultivation of an animal cell *in vitro*. (*See* arguments set forth at pages 4-6 in the Amendment and Reply Under 37 C.F.R. § 1.111, filed October 15, 2002.)

The Examiner stated that:

the use of applicant's agar¹ to cultivate animal cells is considered a recitation of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art.

(Paper No. 18, page 3.)

The phrase "wherein said medium is capable of supporting the cultivation of an animal cell *in vitro*," is not simply a recitation of intended use. This phrase, in light of the specification, would be interpreted by one of ordinary skill in the art as meaning that the claimed cell culture media comprises, in addition to at least one of the specified non-animal or plant-derived ingredients, certain components that allow for the cultivation of an animal cell. (*See, e.g.*, specification at pages 11-19 (demonstrating the types of considerations that

¹The claims are directed to cell culture media, not to agar. It is unclear why the Examiner has interpreted the claims as being directed to agar. Clarification is requested.

go into the formulation of an animal culture medium), *see also* Allen R. Liss, *Methods for Preparation of Media, Supplements and Substrate for Serum-Free Animal Cell Culture* (cited and incorporated by reference in the specification at page 10, lines 13-15.))

The compositions in the DIFCO manual contain only (1) infusion from potatoes, (2) dextrose, and/or (3) agar. Media containing these ingredients would not support the growth of animal cells. Thus, the DIFCO manual does not teach or suggest all of the elements of Applicants' claims. Applicants therefore respectfully request that the rejection of claims 1, 2, 12, 13, 26 and 34-38 under 35 U.S.C. § 102, be reconsidered and withdrawn.

III. Claim Rejections Under 35 U.S.C. § 103

A. DIFCO Manual in light of Dyas in view of Gibco Catalogue

Claims 1-5, 8-13, 26, 29-32 and 34-38 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over the DIFCO manual in light of Dyas, in view of Gibco BRL Life Technologies Catalogue and Reference Guide (hereinafter "Gibco Catalogue"). (*See* Paper No. 18, page 4.) Applicants respectfully traverse this rejection.

Claims 1, 3, 4, 12, 34 and 35 are directed to cell culture media and compositions comprising at least one non-animal or plant-derived peptide, wherein the non-animal or plant derived peptide(s) are derived from the group consisting of fungi, yeast, rice, potato, corn, and aloe vera. Claims 2, 5, 8-11, 13, 29-32 and 36-38 are directed to cell culture media, and compositions comprising at least one non-animal or plant-derived lipid or at least one non-animal or plant-derived fatty acid, wherein the non-animal or plant derived lipid(s) or fatty

acid(s) are derived from the group consisting of bacteria, fungi, yeast, rice, potato, corn, and aloe vera.

The Gibco Catalogue does not disclose a peptide derived from fungi, yeast, rice, potato, corn or aloe vera, nor does it disclose a lipid or fatty acid derived from bacteria, fungi, yeast, rice, potato, corn or aloe vera. Therefore, the compounds listed in the Gibco Catalogue does not describe a cell culture medium or composition that falls within the scope of the present claims.

In addition, as discussed above, the present claims are directed to cell culture media and compositions that are capable of supporting the cultivation of an animal cell *in vitro*. A person of ordinary skill in the art would appreciate the kinds of ingredients that would be included in a culture medium so that the medium is capable of supporting the cultivation of an animal cell. The compositions disclosed in the DIFCO manual are used to culture only yeasts and molds; they would be ineffective at supporting the cultivation of an animal cell. Thus, combining the ingredients from the Gibco Catalogue with the composition in the DIFCO manual would not produce a cell culture medium capable of supporting the cultivation of an animal cell *in vitro*. (See arguments set forth at pages 7-8 in the Amendment and Reply Under 37 C.F.R. § 1.111, filed October 15, 2002.)

Moreover, in order to establish a *prima facie* case of obviousness, there must be some suggestion, teaching or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. See *In re Rouffet*, 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1457-58 (Fed. Cir. 1998). Evidence of a suggestion, teaching, or motivation to combine references must be "clear and particular." See *In re Dembiczak*, 175 F.3d 994, 999, 50

USPQ2d 1614, 1617 (Fed. Cir. 1999). "Broad conclusory statements regarding the teaching of multiple references, standing alone, are not 'evidence.'" *Dembiczak*, 175 F.3d at 999, 50 USPQ2d at 1617. Since the Examiner has not presented any evidence to suggest that a person of ordinary skill in the art would have been motivated to combine or modify the DIFCO manual and/or the Gibco Catalogue, a *prima facie* case of obviousness has not been established.

The Examiner stated that:

[T]he motivation to add these ingredients [from the Gibco Catalogue] is found by what would be known by a person of ordinary skill in the art. A person of ordinary skill in the art would expect that culture media can be modified by adding different ingredients to the media. This is a routine practice in the art.

(Paper No.18, page 4.) This is not a legally sufficient demonstration of a motivation to combine references. The Examiner has not provided any indication of "what would be known by a person of ordinary skill in the art." In addition, the statement that "[a] person of ordinary skill in the art would expect that culture media can be modified by adding different ingredients to the media" does not indicate a *clear and particular* suggestion for one of ordinary skill in the art to combine the disclosure of the DIFCO manual with that of the Gibco Catalogue. Whether or not a person of ordinary skill in the art would "expect" that culture media can be modified does not indicate that a person of ordinary skill in the art would be *motivated* to modify culture media. Nor does it indicate that a person of ordinary skill in the art would have been motivated to *specifically* combine the disclosure of the DIFCO manual with that of the Gibco Catalogue and thereby arrive at the claimed culture media. The statements set forth in the Office Action cannot support a *prima facie* case of obviousness.

Since there is no motivation to combine the DIFCO manual and the Gibco Catalogue, and since the combination, in any event, would not have resulted in a medium that falls within the scope of Applicants' claims, Applicants respectfully request that this rejection of claims 1-5, 8-13, 26, 29-32 and 34-38 under 35 U.S.C. § 103(a) be reconsidered and withdrawn.

B. U.S. Patent No. 5,122,469 in view of Dyas and Gibco Catalogue

Claims 1-13, 18-21, 26, 29-32 and 34-38 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 5,122,469 (hereinafter "the '469 patent") in view of Dyas and the Gibco Catalogue. (*See* Paper No. 14, page 4.) Applicants respectfully traverse this rejection.

The Examiner stated that "the ['496] patent clearly states that their inventive serum media can contain lipoic acid, peptone, and lipids. Therefore, the patent clearly encompasses a culture medium for the cultivation of mammal cells that contains all of these ingredients." (Paper No. 18, page 5.) Applicants respectfully disagree and submit that this assertion does not support the rejection under § 103.

Claims 1, 3, 4, 6, 12, 18, 19, 34 and 35 are directed to cell culture media and compositions comprising at least one non-animal or plant-derived peptide, wherein the non-animal or plant derived peptide(s) are derived from the group consisting of fungi, yeast, rice, potato, corn, and aloe vera. Claims 2, 5, 7-11, 13, 20, 21, 29-32 and 36-38 are directed to cell culture media and compositions comprising at least one non-animal or plant-derived lipid or at least one non-animal or plant-derived fatty acid, wherein the non-animal or plant

derived lipid(s) or fatty acid(s) are derived from the group consisting of bacteria, fungi, yeast, rice, potato, corn, and aloe vera.

The '496 patent does not teach or suggest the inclusion of a peptide derived from fungi, yeast, rice, potato, corn or aloe vera, nor does it teach or suggest the inclusion of a lipid or fatty acid derived from bacteria, fungi, yeast, rice, potato, corn or aloe vera. Therefore, the Examiner's statement that the medium of the '496 patent can contain lipoic acid, peptone and lipids does not support the rejection under § 103.

The Examiner stated that "since applicant's claims are drawn to composition claims and not drawn to methods of making a culture medium, the source of the plant peptides and lipids would not lend a patentable difference as long as the claimed elements are present in the reference." (Paper No. 18, page 5.) Applicants respectfully disagree. The chemical and biological characteristics of peptides and lipids vary based on the source from which they are derived. For example, a given peptide from one organism will have a different amino acid sequence than in another organism. Moreover, the types of peptides and lipids will also vary depending on the source. Thus, the source of the peptides and lipids specified in the claims cannot be ignored when assessing patentability.

Moreover, an obviousness rejection cannot be properly made unless there is a "clear and particular" motivation suggesting to one of ordinary skill in the art to combine or modify the reference disclosures. *See Rouffet*, 149 F.3d at 1357, 47 USPQ2d at 1457-58; *Dembiczak*, 175 F.3d at 999, 50 USPQ2d at 1617 (Fed. Cir. 1999). The Examiner has not provided any specific evidence to indicate that a person of ordinary skill in the art would have been motivated to modify or combine the cited references. Therefore, a *prima facie* case of obviousness has not been established.

The Examiner stated that "there is considered to be sufficient motivation [to combine the Gibco Catalogue and the '496 patent] based on what was known in the art." (Paper No. 18, page 5.) To support this assertion, the Examiner referred to the statements set forth in paragraph 9 (page 4) of the Office Action. As noted above, the cited statements in paragraph 9 are not supported by any evidence and they do not demonstrate a *specific* suggestion to combine or modify the references. The rationale behind the rejection is therefore legally insufficient to establish a *prima facie* case of obviousness.

Since the Examiner has not presented any clear and particular evidence to indicate that a person of ordinary skill in the art would have been motivated to combine or modify the cited references, a *prima facie* case of obviousness has not been established. Therefore, Applicants respectfully request that the rejection of claims 1-13, 18-21, 26, 29-32 and 34-38 under 35 U.S.C. § 103(a) be reconsidered and withdrawn.

Conclusion

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

A handwritten signature in black ink, reading "Frank R. Cottingham". The signature is fluid and cursive, with a long, sweeping horizontal line at the end.

Frank R. Cottingham
Attorney for Applicants
Registration No. 50,437

Date: APR. 30, 2003

1100 New York Avenue, N.W.
Washington, D.C. 20005-3934
(202) 371-2600

SKGF_DC1:127937.1